The Proposed CREATES Act: How to Fix Legislative Barriers to Competition at the FDA

Written Statement of

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on

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Introduction

Poorly drafted regulations, especially in heavily regulated industries, can create opportunities for anticompetitive abuse. Established companies know how to navigate regulatory mazes, and the complexities of such regimes create innumerable opportunities for nominal compliance at the expense of competition, innovation, and new entry.

The legislative and regulatory impulse when faced with deeply entrenched regulations and their competitive manipulations is often to pile on, either with even more-complex regulatory amendments or else antitrust enforcement that side-steps the root problem, focusing on "fixing" allegedly anticompetitive conduct rather than reforming the underlying laws that facilitate it.

But the government has a questionable track record in promoting competition, not infrequently adopting policies seemingly tailor-made to perpetuate, rather than constrain, harmful conduct.

The FDA Act and the regulations promulgated under it by the agency stand as Exhibit A in this regard. Last year's controversy over Mylan Pharmaceuticals' price hike on the EpiPen, for example, is symptomatic of the problem. The market for pharmaceuticals is complicated, but one thing seems clear in the pricing controversy: the FDA has been an effective ally for Mylan in keeping out competitive producers of generic epinephrine auto-injectors. Drug safety is important, of course, but since 1962 the FDA has also reviewed drugs for "efficacy," which introduced massive delay and uncertainty, arguably without concomitant benefit. And the FDA's approval and oversight processes for generics and biosimilars, although improved since 1962,

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continue to impede effective entry. Thus, with the field clear of competitors, it is no surprise that Mylan was able to raise prices. Only following the angry public outcry did the FDA finally accelerate its review process and approve a competing product last month.

But efficacy review is not the FDA's only regulatory *cul de sac* through which pharmaceutical manufacturers can employ regulatory policies to keep unwanted competitors off the block. In particular, one aspect of the FDA's drug safety oversight regime has emerged as a device for some manufacturers to delay generic entry: the Risk Evaluation and Mitigation Strategies, or "REMS," program.

What I will refer to collectively as the FDA Act's REMS program comprises two elements that are relevant here: First, it requires branded drug manufacturers to make samples of their drugs available to would-be generic entrants so that they can use them in the lengthy safety and efficacy testing process required to secure FDA approval. Second, it requires brand drug companies to adopt a concerted set of practices and policies aimed at mitigating the risks inherent in the use of most drugs, and additional, more restrictive practices to ensure the safe use of particularly dangerous or addictive drugs — the so-called "REMS with ETASU" ("Elements to Assure Safe Use"). The program also requires that brand manufacturers allow generic entrants to share in these enhanced mitigation processes in order, presumably, to streamline the process and economize on compliance costs.

By forcing collaboration between competitors, the REMS program is practically tailor-made for problems. Although the FDA Act specifically prohibits the use of these regulatory elements to block lower-cost, generic alternatives from entering the market (of course),[1] almost immediately following the law's enactment, a small handful of branded pharmaceutical companies began using REMS for just that purpose (also, of course).

Some (now-former) FTC commissioners, among others, have raised concerns that brand drug manufacturers can (and do) take advantage of these provisions by adopting tough negotiating positions that, they allege, amount to anticompetitive

[1] 21 U.S.C. § 355-1(f)(8).

exclusion requiring agency enforcement.[2] I believe that that would be decidedly the wrong approach to dealing with the issue. *These are not properly antitrust problems; they are problems of poor regulatory design.*

But it is also true that the program itself exists to implement an underlying policy that may be even worse, and it is likely that reforming a few key elements of the program would help prevent such abuses — but Congress should adopt more fundamental policy changes, as well.

The first part — sharing samples — cannot easily be fixed by removing the required collaboration, at least not without completely revamping (or removing) the FDA's drug safety and efficacy oversight function (however desirable reform of these functions would be). But the second — sharing REMS programs — can be.

Enter the CREATES Act…

Thus it is heartening that Senate Antitrust, Competition Policy, and Consumer Rights Subcommittee Chairman, Mike Lee, and several of his Judiciary Committee colleagues (Sens. Leahy, Grassley, Klobuchar, Feinstein, McCaskill, Collins, McCain, Blumenthal, Whitehouse, Cotton, and Durbin), along with House Regulatory Reform, Commercial, and Antitrust Law Subcommittee Chairman, Tom Marino, and his colleague, Rep. Cicilline, have introduced a bill — the CREATES Act of 2017[3] — that would seem to offer the right kind of relief, aimed at fixing defective statutory language and regulatory policies, while explicitly eschewing expanded antitrust enforcement.

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[2] *See, e.g.*, FTC Chairman Edith Ramirez, *Prepared Statement of the Federal Trade Commission*, Before the U.S. House of Representatives Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Hearing on "Oversight of the Enforcement of the Antitrust Laws" (Nov. 13, 2015), *available at* https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-oversight-enforcement-antitrust-laws-presented/131115antitrustlawtestimony.pdf.

[3] The Creating and Restoring Equal Access to Equivalent Samples Act of 2017, S.974 (CREATES Act of 2017), *available at* https://www.congress.gov/bill/115th-congress/senate-bill/974; H.R.2212 (CREATES Act of 2017), *available at* https://www.congress.gov/bill/115thcongress/house-bill/2212 (the "CREATES Act").

The proposed legislation would both ameliorate the bad incentives created by the first part of the law, and remove the faulty, underlying policy that creates the problem in the second.

And it would do so without resorting to an inappropriately invigorated antitrust regime. As the bill notes:

> While the antitrust laws may address actions by license holders who impede the prompt negotiation and development on commercially reasonable terms of a single, shared system of elements to assure safe use, ***a more tailored legal pathway would help ensure that license holders negotiate such agreements in good faith and in a timely manner***, facilitating competition in the marketplace for drugs and biological products.[4]

The legislative solution put forward in the CREATES Act targets the right culprit: the poor regulatory drafting that permits possibly anticompetitive conduct to take place. Moreover, the bill refrains from creating a *per se* rule, instead implementing several features that should still enable brand manufacturers to legitimately restrict access to drug samples when appropriate.

In essence, the proposed CREATES Act introduces a third party (in this case, the Secretary of Health and Human Services (presumably acting through the Commissioner of Food and Drugs) who is capable of determining whether an eligible generic manufacturer is able to comply with REMS restrictions — thus bypassing any bias on the part of the brand manufacturer who would otherwise be tasked with making that determination under the FDA Act. Where the Secretary determines that a generic firm meets the REMS requirements (and is thus eligible to receive samples), the bill also creates a narrow cause of action (for this narrow class of plaintiffs) against certain brand manufacturers who nevertheless misuse the process to delay competitive entry.

With respect to shared REMS, the proposed bill adopts an even more direct approach, altering the language introduced into the FDA Act by the 2007 FDA

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[4] *Id.* at § 2(9) (emphasis added).

Amendments Act ("FDAAA")[5] to remove the regulatory dynamic that creates the possibility of anticompetitive conduct in the first place.

… And exit antitrust

In order to understand the real value of the CREATES Act, it is important to recognize that antitrust law has historically had an uneasy relationship with other regulatory schemes. Not least because of the Supreme Court's *Trinko*[6] and *Credit Suisse*[7] decisions, it is a tough case to make that brand manufacturers are violating antitrust laws when they rely upon legal obligations under a regulatory regime that is essentially *designed* to limit generic entry on safety grounds. The issue is all the more properly removed from the realm of antitrust enforcement given that the problem is actually one of *regulatory* failure, not market failure.

Further, antitrust law doesn't impose a duty to deal with rivals except in very limited circumstances.[8] In *Trinko*, for example, the Court rejected the invitation to extend a duty to deal to situations where an existing, voluntary economic relationship was not terminated. By definition this is unlikely to be the case here where the alleged refusal to deal is what prevents the generic from entering the market in the first place. The logic behind *Trinko* (and a host of other cases that have limited competitors' obligations to assist their rivals) was to restrict duty to deal cases to those rare circumstances where refusals to deal reliably lead to long-term competitive harm — not where they amount to perfectly legitimate efforts to compete without giving rivals a leg-up.

But antitrust is such a powerful tool, and such a flexible "catch-all" regulation, that enforcers and regulatory advocates perpetually seek to thwart reasonable judicial limits on its use. As I have written about at length in the past,[9] for example, former

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[5] Public Law 110–85, 121 STAT. 823 (Sep. 27, 2007), *available at* https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf.

[6] Verizon Communications, Inc., v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004).

[7] Credit Suisse Securities (USA) LLC v. Billing, 551 U.S. 264, 282 (2007).

[8] *See, e.g.*, Thomas A. Lambert & Alden F. Abbott, *Recognizing the Limits of Antitrust: The Roberts Court Versus the Enforcement Agencies*, 11 J. COMP. L. & ECON. 791 (2015).

[9] *See, e.g.*, Geoffrey A. Manne, *The FTC's Misguided Rationale for the Use of Section 5 in Sherman Act Cases*, 2 CPI ANTITRUST J. (February 2010), *available at* https://ssrn.com/abstract=1562489;

FTC Commissioner, Tom Rosch, and former FTC Chairman, Jon Leibowitz, were vocal proponents of using Section 5 of the FTC Act to circumvent sensible judicial limits on making out and winning antitrust claims, arguing that the limits were meant only for *private* plaintiffs — not (implicitly infallible) government enforcers. Although no one at the FTC has yet (publicly) suggested bringing a REMS action as a standalone Section 5 case, such an action would be consistent with the sorts of theories that animated past standalone Section 5 cases.

Again, such an approach would serve as an end-run around the reasonable judicial constraints that evolved as a result of judges actually examining the facts of individual cases over time, and is a misguided way of dealing with what is, after all, fundamentally a regulatory design problem.

Finally, it is important to note that the proposed bill completely avoids the question of whether antitrust laws are applicable, leaving that possibility open to determination by courts; it does not *preclude* the possibility of antitrust enforcement — as is appropriate. At the same time, however, by establishing even more clearly the comprehensive regulatory regime governing potential generic entrants' access to dangerous drugs, the bill would, given the holding in *Trinko*, probably make application of antitrust laws here considerably less *likely* — which is *also* appropriate.

The problem of withholding drug samples

To enter into pharmaceutical markets that no longer have any underlying IP protections, generic drug manufacturers must submit to the FDA an Abbreviated New Drug Application (ANDA) for a generic, or an Abbreviated Biologic License Application (ABLA) for a biosimilar, of the brand drug. The purpose is to prove to the FDA that the competing product is as safe and effective as the branded reference product. In order to perform the testing sufficient to prove efficacy and safety, generic and biosimilar drug manufacturers must acquire a sample (many samples, in fact) of the reference product they are trying to replicate.

Geoffrey Manne, *Debunking the "pro-business" rationale for Section 5 enforcement*, TRUTH ON THE MARKET (Feb. 4, 2010), https://truthonthemarket.com/2010/02/04/debunking-the-pro-business-rationale-for-section-5-enforcement/; Geoffrey Manne, *The folly of the FTC's Section 5 case against Google*, TRUTH ON THE MARKET (May 7, 2012), https://truthonthemarket.com/2012/05/07/the-folly-of-the-ftcs-section-five-case-against-google/.

Drugs subject to a REMS with ETASU are often difficult to obtain through market channels and are not otherwise readily available, even for would-be generic manufacturers; safety protocols under a brand drug company's REMS with ETASU typically require the brand manufacturer to restrict distribution of these drugs that present safety or abuse risks. For this narrow class of dangerous or frequently abused drugs, generic manufacturers are forced to comply with any REMS restrictions placed upon the brand manufacturer — even when the terms require the brand manufacturer to tightly control the distribution of its product.

But the drug-sample provision process allows brands considerable leeway to determine whether generic manufacturers are compliant. And given this discretion, it is no surprise that brand manufacturers may be tempted to block competition by citing "safety concerns."

And therein lies the problem. Because the brand manufacturer controls access to its products, it can refuse to provide the needed samples, using its REMS protocols as an convenient cover story.

It is surely true in certain cases that a brand manufacturer is justified in refusing to distribute samples, of course; *some* would-be generic manufacturers certainly do not meet the requisite standards for safety and security. But a REMS program can also create an opportunity for the branded drug manufacturer to take advantage of imprecise regulatory requirements to inappropriately limit access by generic manufacturers, thus delaying or thwarting their ability to enter the market.

It turns out that, in practice, most of the (publicly known) examples of brands refusing to provide samples happen across the board — they preclude essentially *all* generic competition, not just the few firms that might have insufficient safeguards. It is difficult to justify such refusals on the basis of a generic manufacturer's suitability when *all* would-be generic competitors are denied access, including well-established, high-quality manufacturers.

But, for a small number of brand manufacturers, at least, that seems to be how the REMS program is implemented. Thus, for example, one pharmaceutical executive referred to the practice of denying generics samples this way:

> We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make generics], no matter what. But I'm certainly not going to make it easier for them.[10]

As currently drafted, the REMS program gives branded manufacturers the ability to limit competition by stringing along negotiations for product samples for months, if not years.

The CREATES Act solution

The CREATES Act, on the other hand, aims to solve the problem by improving the existing regulatory mechanism and by adding a limited judicial remedy to incentivize compliance under its amended regulatory scheme. In summary:

- The bill creates a cause of action for a refusal to provide samples only where a plaintiff can prove, by a preponderance of the evidence, that certain well-defined conditions are met.
- If a drug is not covered by a REMS, or if the generic manufacturer is specifically authorized, then it can sue the brand manufacturer if it does not receive sufficient quantities of samples on commercially reasonable terms.
- This is not a *per se* offense subject to outsized antitrust damages. Instead, the remedy is a limited injunction ensuring the sale of samples on commercially reasonable terms, enforced through the threat of reasonable attorneys' fees and a monetary fine.
- The bill also gives a brand manufacturer an affirmative defense if it can prove by a preponderance of the evidence that, regardless of its own refusal to supply them, samples were nevertheless available elsewhere on commercially reasonable terms, or where the brand manufacturer is unable to supply the samples because it does not actually produce or market the drug.

The primary remedy is thus limited, injunctive relief to mitigate the risk of improper delay.

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[10] Jon Haas, director of patient access at Turing Pharmaceutical, *quoted in* Ed Silverman, *How Martin Shkreli prevents generic versions of his pricey pill*, STAT PHARMALOT (Oct. 5, 2015), http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/.

But the bill does not simply mandate compliance by branded manufacturers without acknowledging that, in many cases, a brand's refusal to supply samples may be perfectly appropriate. Instead, the bill removes the primary justifications for such delay and also holds the branded manufacturer harmless if the generic competitor turns out to create the sort of safety problems the program was intended to prevent by a) outsourcing a generic's eligibility determination to a third party; b) creating a safe harbor from claims that providing samples in accordance with the bill violates a brand's REMS obligations; and c) adopting a blanket limitation of liability:

> A [brand manufacturer] shall not be liable for any claim arising out of the failure of an eligible [generic manufacturer]to follow adequate safeguards to assure safe use of the [samples] during development or testing activities described in this section, including transportation, handling, use, or disposal of the [samples] by the [generic manufacturer].[11]

The bill also protects brands with an affirmative defense under which they need only show that the product is available for purchase on reasonable terms elsewhere. And damages are available only if a court finds that the brand manufacturer lacked a legitimate business justification for its conduct (which, under the drug safety regime, means essentially a reasonable belief that its own REMS plan would be violated by dealing with the generic entrant). And monetary damages do not include punitive damages.

A note of caution: The devil is in the details

It is true that, in order to make the injunction effective, the CREATES Act would impose a penalty for noncompliance that is not simply commensurate with the harm imposed by delaying generic entry (not least because the bill would allow generic entrants to receive samples in certain circumstances even if withholding them would not, *in fact*, delay entry (for a number of statutory reasons)). There are sound reasons for this, although some caution is warranted.

In order for an injunction to be effective it must impose a penalty for *non*compliance large enough to ensure compliance: The point is *not* compensatory damages, but rather enforcement of the injunction. For that reason, however, and the fact that the

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[11] CREATES Act, *supra* note 3, at § 3(c).

penalty is paid to the generic manufacturer, the significant size of the potential award risks incentivizing generic entrants *themselves* to game the system in order to receive a payout from unmeritorious litigation under the bill.

The relevant question is, as always, the error-cost tradeoff inherent in any policy choice. The CREATES Act imposes an injunction and assigns a penalty that shifts relative bargaining power in the FDA regulatory environment toward generic entrants and away from brand manufacturers by some amount. Whether the specific penalty contemplated ("not [] greater than the revenue that the [brand manufacturer] earned on the covered product during the period")[12] and the other specific terms of enforcement shift the relative bargaining power the *optimal* amount is not clear. As far as I know the penalty amount and other terms were arrived at without careful consideration of the relevant data, and are more of an educated guess than a careful calibration.

While I believe that imposing a penalty large enough to deter bad conduct is appropriate (and it is certainly possible that the current bill gets it right), I do not know (and I doubt anyone knows) if *this* penalty is appropriately calibrated to reflect the current risk of harm *as well as* the risk of harm from possible abuse by generic entrants of their new bargaining power under the bill. In order to ensure that the legislation does more good than harm it is important to know this, and I urge members of both subcommittees to collect and assess the relevant information. I do believe that the overall structure of the CREATES Act offers a sound, and limited, solution to a structural problem of the regulatory environment. But that does not mean that it is necessarily perfect in every detail.

The shared REMS problem

The REMS program itself was introduced as part of the FDAAA in 2007.[13] Following the withdrawal of the arthritis pain reliever, Vioxx, from the market because of a post-approval linkage of the drug with increased heart attack risk, the FDA was under

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[12] *Id.* at § 3(b)(4)(B).

[13] The REMS program is codified in the FDA Act at 21 U.S.C. § 355-1.

considerable fire,[14] and there was a serious risk that fewer and fewer net beneficial drugs would be approved. The REMS program was introduced by Congress as a mechanism to ensure that society could continue to reap the benefits from risky drugs and biologics — rather than the FDA preventing them from entering the market at all.[15] It accomplishes this by requiring (among other things) that brands and generics adopt appropriate safety protocols for distribution and use of drugs, particularly when a drug has the potential to cause serious side effects, or has an unusually high abuse profile.

That is all well and good. But the Act also requires that brand manufacturers *share* their own REMS processes with generic entrants on commercially reasonable terms. The *shared* REMS requirement may have been included by Congress in order to economize on compliance costs, or on the theory that established brand manufacturers were more likely to adopt effective programs (and forced sharing would confer that enhanced effectiveness on generics, as well). In any case, the law effectively makes collaboration with brand manufacturers a prerequisite for generic entrants.

This is particularly true as it has been implemented by the FDA, which virtually never grants waivers for generics to operate their own REMS. The reasons for the FDA's reluctance to grant such waivers are unclear, but it seems likely it has something to do with the agency's continued concern for its own reputation. Certainly, one would think, granting a waiver in the event of a negotiating impasse (or even, when it occurs, intentional intransigence by brand manufacturers) would regularly meet the statute's requirement that the FDA "permit the applicant to use a different, comparable aspect of the elements to assure safe use if… the burden of creating a single, shared system outweighs the benefit of a single, [shared] system…."[16] In any case, as noted, such waivers are essentially never granted, even where both parties would prefer operating

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[14] *See* John E. Calfee, *Reform without Reason: What's Wrong with the FDA Amendments Act of 2007*, AEI Health Policy Outlook No. 12 (Sep. 2007), *available at* https://www.aei.org/wp-content/uploads/2011/10/20070927_HPOcorrected_3.pdf.

[15] *See* Stacey L. Worthy, *Don't sell out safety: a call to preserve risk evaluation and mitigation strategies to reduce harm to patients and the public in the U.S.*, 9(2) J. PHARM. POL'Y & PRACT. 1 (Dec. 2016), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4721201/.

[16] 21 U.S.C. § 355–1(h)(8)(i)(1).

under separate programs to protracted, contentious, and possibly strategic negotiations.

The result is that the law and the pattern of enforcement by the FDA combine to create an opportunity for brand manufacturers to further delay entry, because they impose on generics a duty to enter into sharing arrangements without perfectly specified terms, and without waiver, thus giving brands an opportunity to string out negotiations or impose unreasonable terms. As important, the situation also imposes significant — and seemingly unnecessary — costs on brands.

But the *fundamental* problem is created by the shared requirement in the first place — which effectively imposes on the parties a duty to deal — and the FDA's unwillingness to allow generics to go it alone when mutually agreeable terms of a deal prove difficult to reach.

While a generic's ability to piggyback on a brand manufacturer's program surely does reduce costs for the generic (and arguably increases the likelihood of entry, at the margin), that mode of cost-cutting is as improper as it would be if the law simply mandated that generic entrants be allowed to occupy a brand manufacturer's offices rent free, conscript its researchers, or co-opt its marketing.

Moreover, there is no evidence that shared REMS programs are more or less effective than separate ones. The problem here is the statutory shared REMS requirement, and the practical limitations on the FDA's incentives to grant waivers from it.[17]

For all of these reasons, the appropriate fix is revision or removal of the offending language that requires brand manufacturers and generic entrants to enter into shared REMS programs.

And, indeed, rather than doubling down on the statute's quixotic effort to force competitors to negotiate and collaborate in order to economize on costs, the CREATES Act simply explicitly permits generics to use a separate REMS system without a waiver, provided it meets the statute's safety requirements to the FDA's satisfaction. This removes a brand manufacturer's ability to withhold agreement on

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[17] *Id.*

terms — *and* it mitigates the unnecessary costs imposed on brand manufacturers of complying with the FDAAA's forced sharing provisions. As the proposed bill notes:

> ***Clearer regulatory authority to approve different systems that meet the statutory requirements to ensure patient safety, however, would limit the effectiveness of bad faith negotiations*** over single, shared systems to delay generic approval. At the same time, clearer regulatory authority would ensure all systems protect patient safety.[18]

It is worth noting that, in this way, the CREATES Act mitigates the risk of holdup by branded incumbents without trading it for the risk of hold*out* by generic entrants — unlike the bill's solution to the drug samples problem, which does necessitate weighing this tradeoff.

Conclusion

Ultimately the proposed bill would effect a well-thought-out and targeted fix to an imperfect regulation that facilitates arguably anticompetitive conduct by a few bad actors. It accomplishes this without trampling on the courts' well-established antitrust jurisprudence, and seemingly (subject to analysis of the data) without imposing excessive cost or risk on the majority of brand manufacturers that behave perfectly appropriately under the law.

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[18] CREATES Act, *supra* note 3, at § 2(10) (emphasis added).

Author Bio

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Geoffrey A. Manne is the founder and executive director of the International Center for Law and Economics (ICLE), a nonprofit, nonpartisan research center based in Portland, Oregon. He is also a distinguished fellow at Northwestern Law School's Searle Center on Law, Regulation, & Economic Growth. In April 2017 he was appointed by FCC Chairman Ajit Pai to the FCC's Broadband Deployment Advisory Committee, and he recently served for two years on the FCC's Consumer Advisory Committee.

Mr. Manne earned his JD and AB degrees from the University of Chicago and is an expert in the economic analysis of law, specializing in competition, telecommunications, consumer protection, intellectual property, and technology policy.

Prior to founding ICLE, Manne was a law professor at Lewis & Clark Law School. From 2006-2009, he took a leave from teaching to develop Microsoft's law and economics academic outreach program. Manne has also served as a lecturer in law at the University of Chicago Law School and the University of Virginia School of Law. He practiced antitrust law and appellate litigation at Latham & Watkins, clerked for Hon. Morris S. Arnold on the 8th Circuit Court of Appeals, and worked as a research assistant for Judge Richard Posner. He was also once (very briefly) employed by the FTC.

Mr. Manne's publications have appeared in numerous journals including the Journal of Competition Law and Economics, the Harvard Journal of Law and technology, the Supreme Court Economic Review, and the Arizona Law Review, among others. With former FTC Commissioner, Joshua Wright, Manne is the editor of a volume from Cambridge University Press entitled, COMPETITION POLICY AND INTELLECTUAL PROPERTY LAW UNDER UNCERTAINTY: REGULATING INNOVATION. Manne has also testified on several occasions before Congress and at the FCC and FTC, and he regularly files written comments and amicus briefs on key antitrust, IP, and telecommunications issues. His analysis is frequently published in popular print and broadcasting outlets such as the Wall Street Journal, Wired, Foreign Affairs, NPR, and Bloomberg, among others.

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